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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/913,443	08/14/2001	Jack Price	GJE-74	9647

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EXAMINER	
QIAN, CELINE X	
ART UNIT	**PAPER NUMBER**
1636	

DATE MAILED: 11/02/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/913,443	PRICE, JACK	
	Examiner	Art Unit	
	Celine X Qian	1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 August 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-6,10-13 and 15-20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-6,10-13 and 15-20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *8/24/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-6, 10-13 and 15-20 are pending in the application.

This Office Action is in response to the Amendment filed on 8/24/04.

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 8/24/04 has been entered.

Response to Amendment

Claims 1-6, 10-13 and newly added claims 15-20 stand rejected under 35 U.S.C.112 1st paragraph for reasons set forth of the record mailed on 2/25/04 and further discussed below.

Response to Arguments

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-6, 10-13 and newly added claims 15-20 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to

enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

In response to this rejection, Applicants argue that the Chopp abstract suggests hematopoietic stem cells have the potential to develop into functional neural cells because the donor cells express markers that are specific to neuronal cells following transplantation. Applicants assert that such markers are commonly used to identify stem cells and to characterize differentiated cell types such as neurons and astrocytes according to the previously cited NIH publication. Applicants further argue that the NIH publication does not indicate that mouse and human cells exhibit entirely different differentiation pattern *in vivo*, and it indicates that adult stem cells appear to have the capability to differentiate into tissues other than the ones from which they originated. Furthermore, Applicants argue that the NIH publication does not indicate that stem cell transplantation would not work. Moreover, Applicants argue that there are many proposed therapies using organic chemicals based solely on *in vitro* data, whereas there is no evidence in the present case that the animal model will not be predictable of *in vivo* success in human patients. Applicants also argue that Mezey reference cited by the Examiner does not provide evidence of difficulty in using bone marrow cells for therapy, but rather just an indication for requiring growth factor when specific differentiated cells are required. Applicants assert that the claimed method does not require obtaining distinct cell types prior to administration. Lastly, Applicants argue that an application for patent does not require the claimed method of treatment to show a cure of the disease or clinical efficacy. Applicants thus conclude that the claimed method is enabled by the instant specification.

The above arguments have been fully considered but deemed unpersuasive. The reasons for the enablement rejection were discussed in detail in the office actions mailed on 7/3/03 and 2/25/04. Applicant is reminded that the rejection is based on an overall analysis of the wands factors, including the nature of the invention, the breadth of the claims, the state of the prior art and the level of predictability in the art, the amount of direction provided by the inventor and the existence of working examples, and whether the quantity of experimentation needed to make or use the invention based on the content of the disclosure is "undue", rather than a single technical difficulty based on the prior art. The state of art at the time of filing indicates that the stem cell therapy is unpredictable due to factors discussed previously (see pages 4-5 of the previous office action, especially about Parkinson's disease). Although Chopp et al. teaches that the transplanted hematopoietic stem cells expresses neuronal or astrocytic phenotype, this reference does not teach whether these cells would develop into fully functional neurons and/or such transplantation would achieve therapeutic effect on any type of sensory, motor/cognitive deficit. The breadth of the claim encompasses a method of treating any type of sensory, motor/cognitive deficit by administering a hematopoietic stem cell intracerebrally. Although Applicant does not have to show complete cure of the disease or clinical efficacy of said method, Applicant has to demonstrate that the sensory, motor/cognitive deficit can be treated by the claimed method without undue experimentation. However, the specification does not teach any therapeutic effect can be achieved by the claimed method. Although the markers are indicative of a specific cell type according to the teaching of NIH publication, the therapeutic effect is necessary since the claimed invention is directed to a method of treating a sensory, motor and/or cognitive disease.

As discussed in the previous office action, the NIH publication and Mezey et al. indicate that not all information from mouse stem cells can be translated to human cells. The example of proposed therapies using organic chemicals based solely on *in vitro* data is not relevant in the instant case because it is not within the same art. The mechanism of action of an organic chemical such as pharmacokinetics and pharmacodynamics is well studied and such experimentation is considered routine in the art, whereas the stem cell technology, especially therapy, is still in its infancy and is considered to be an unpredictable art at present. The Weimann reference cannot be relied on to support the enablement of the claimed invention because the claimed invention has to be enabled at the time the invention was made. In the instant case, Weimann et al. was published in the year 2003, 4 years after the priority date of the current application. Moreover, this reference also fails to teach that the transplantation of a human hematopoietic stem cell would achieve any therapeutic effect in treating any type of sensory, motor/cognitive deficit. Based on the teaching of prior art and the specification, although the hematopoietic cell can be transplanted intracerebrally as indicated by Applicant, whether it can treat any sensory, motor/cognitive deficit is unpredictable. Therefore, for reasons set forth in the previous office action and above, one skilled in the art would have to engage in undue experimentation to practice the method as claimed. As such, the claimed method is not enabled.

Newly added claims 15-20 are rejected for same reasons as discussed above.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Celine X Qian whose telephone number is 571-272-0777. The examiner can normally be reached on 9:30-6:00 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel Ph.D. can be reached on 571-272-0781. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Celine Qian, Ph.D.